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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,550	SONG ET AL.	
	Examiner	Art Unit	
	CATHY K. WORLEY	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) *4-6,16-18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 7-15, and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on Dec. 17, 2009, has been entered.

2. Claims 2 and 19 have been cancelled.

Claims 1, 3-18, and 20-25 are pending.

Claims 4-6, 16-18, 20, and 21 are withdrawn.

3. Claims 1, 3, 7-15, and 22-25 are examined in the present office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 7-15, and 22-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant's arguments in the response filed on Dec. 17, 2009, were fully considered but were not found to be persuasive.

The claims are broadly drawn to a construct comprising a promoter sequence that is a functional equivalent homolog having at least 98% identity to SEQ ID NO:1 or having a fragment of SEQ ID NO:1 comprising a sequence from about base pair 300 to about base pair 583 of SEQ ID NO:1 (which would be 284 base-pairs in length), or a fragment of SEQ ID NO:1 having the promoter activity of SEQ ID NO:1, and to vectors, organisms, plants, cell-cultures, parts, or propagation materials comprising said construct. A "fragment" can be as small as a di-nucleotide.

The Applicants describe the promoter of the *Pisum sativum* ptxA gene as SEQ ID NO:1 or its complement (see page 4, lines 42-43). They describe the expression patterns in transgenic Arabidopsis and canola in a Table that indicates high expression in seedlings, medium expression in leaves, roots, flowers and seed pods, and no expression in seeds for Arabidopsis; and high expression in seedlings and leaves, medium expression in flowers, low expression in seed pods, and no expression in seeds for Canola (see Table 1 on page 56). The construct in Example 2 is presumed to comprise SEQ ID NO:1, although this is not expressly stated in the specification. They describe motifs that were identified using computer analysis of the nucleotide sequence of SEQ ID NO:1 (see pages 59-60). They describe a construct comprising a chimeric promoter comprising the ptxa promoter and the maize ubiquitin intron, and they describe the expression pattern from this chimeric

promoter as high in embryogenic calli and *in vitro* root, and medium in *in vitro* leaves and plantlets (see Example 17 and Table 3 on page 62).

The essential feature of the promoter recited in the instant claims is that it has promoter activity at least in leaves but not in seeds (see claim 1) or that it has the same promoter activity as SEQ ID NO:1 (see part "d" of claim 1).

284 base-pair long fragments of a nucleic acid that has promoter activity (such as SEQ ID NO:1) cannot predictably be assumed to also have the same promoter activity. Di-nucleotide fragments of a nucleic acid with promoter activity do not have promoter activity.

Deletion analysis of various promoters have shown that even DNA segments from the portion of a promoter region containing sequence elements thought to be most important (*e.g.*, the TATA-box) need to be longer than two base pairs. Maiti et al (1997, Transgen. Res., 6:143-156), in studies on a figwort mosaic virus promoter, found that smallest portion upstream of the transcriptional start site of that would support transcription was 198 basepairs long; segments of 73 and 37 basepairs did not work (Fig. 4). Doelling et al (1995, Plant J. 8:683-692) found that the minimal rRNA promoter of *Arabidopsis thaliana* is at least 33 nucleotides long (Fig. 1). These studies were directed to the ability to initiate transcription without any requirements about a specific tissue specificity.

The instant claims require that the promoter is active in leaves but not in seeds, or that the promoter have the same activity as SEQ ID NO:1, which has a

complex tissue-specificity. This specificity may involve both positive and negative regulatory elements (see Bustos et al (The EMBO Journal (1991) Vol. 10, pp. 1469-1479). Therefore, if the absence of activity in seeds depends upon a repressor, this absence of activity in seeds would be lost if the negative *cis* element is mutated or deleted (see Bustos et al, page 1471 which discusses negative regulatory elements).

Mutation of promoter sequences also produces unpredictable results. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724).

Identification of the functional parts of promoters is unpredictable. Chen et al (2000, Sex. Plant Reprod. 13:85-94) teach that two promoters with similar expression patterns have major differences in the expression elements required for expression in various flower parts (pg 92, right column, last two paragraphs).

The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

The instant application does not describe any particular cis elements that are required for the tissue specificity of SEQ ID NO:1 or, specifically, for the lack of activity in seeds.

They do not describe expression patterns for transformed maize past the T_o plantlet stage. They do not describe any nucleic acids with 98% identity to SEQ ID NO:1 that retain promoter activity, other than the nucleic acid of SEQ ID NO:1 itself. They do not describe any expression pattern for the promoter of bases 300 to 583 of SEQ ID NO:1. They do not describe expression patterns for "a fragment of SEQ ID NO:1" which can be as small as a dinucleotide.

The recitation of a sequence having at least 98% identity to SEQ ID NO:1 encompasses nucleic acids having additions, deletions, substitutions or insertions relative to SEQ ID NO:1. The Applicants do not describe any additions, deletions, substitutions, or insertions within SEQ ID NO: 1 that retain promoter activity equivalent to the promoter activity of SEQ ID NO:1.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See

University of California v. Eli Lilly and Co., 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants fail to describe a representative number of nucleic acid molecules with promoter activity that comprise a nucleotide sequence with additions, deletions, substitutions or insertions into SEQ ID NO:1. The Applicants only describe the nucleic acid of SEQ ID NO:1 which was shown to have promoter activity in transgenic plants. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of nucleic acids that are sufficient for having promoter activity equivalent to the promoter activity of SEQ ID NO:1. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for promoter activity equivalent to the promoter activity of SEQ ID NO:1, it remains unclear what features identify nucleic acids capable of such activity. Since the genus of nucleic acids has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Isolated nucleic acids that have at least 98% identity with SEQ ID NO:1 encompass over 4^{17} nucleotide molecules with additions, deletions, substitutions or insertions into SEQ ID NO:1. This recitation encompasses multitudes of molecules, many of which would not comprise promoter activity equivalent to the activity of SEQ ID NO:1, and most of which were not in the possession of the Applicant at the

time of filing. The Applicants have reduced to practice only one promoter (presumed to be SEQ ID NO:1) in an experiment that demonstrates promoter activity in leaves but not in seeds. Accordingly, the specification fails to provide an adequate written description to support the genus of nucleic acids with promoter activity equivalent to SEQ ID NO:1 that comprise a nucleotide sequence with 98% identity to SEQ ID NO:1 as set forth in the claims. (See Written Description guidelines published in 2008 online at http://www.uspto.gov/web/menu/written.pdf).

APPLICANT'S ARGUMENTS

The Applicant argues that even if a di-nucleotide can be a "fragment", then if it does not have the promoter activity of SEQ ID NO:1, it would not be encompassed by the claims (see paragraph bridging pages 1-8 of the response). This is not persuasive, however, because the written description is based on the fact that one of skill in the art would not know which fragments have the same promoter activity of SEQ ID NO:1 and which fragments do not have the same promoter activity of SEQ ID NO:1, because there has not been an adequate disclosure of motifs or cis elements that are necessary to produce the activity of SEQ ID NO:1. The fact that di-nucleotides without promoter activity are not encompassed by the claims is why the Examiner did not apply an art rejection. That fact does not support written description of the large genus of molecules encompassed by the claims.

The Applicant argues that they have actually reduced to practice expression constructs with SEQ ID NO:1 (see third paragraph on page 8). The Examiner

agrees that the promoter of SEQ ID NO:1 has been reduced to practice. The Examiner does not agree that this is sufficient for providing written description support for the extremely broad claims.

The Applicant argues that they have provided a fragment from about base pair 300 to about base pair 583; and a fragment from about base pair 300 to about base pair 828 as functional equivalents (see paragraph bridging pages 8-9 of the response). This is not persuasive, however, because these fragments have not been reduced to practice to demonstrate that they have the same promoter activity as SEQ ID NO:1.

The Applicant argues that there has never been a requirement that every species encompassed by a claim must be disclosed or exemplified, and that it should not matter that the transformed maize were not grown past the T_0 stage (see second paragraph on page 9 of the response). This is not persuasive, however, because the claims include the limitation that the promoter is active in leaves but not in seeds; and there is evidence that the tissue specificity for this particular promoter in different plant species is different; therefore, it is possible that the property of expressing in leaves but not in seeds does not hold true for monocots and is only true for dicots.

Enablement

5. Claims 1, 3, 7-15, and 22-25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising a fragment of SEQ ID NO:1 wherein said fragment comprises promoter activity in a plant, and wherein the promoter activity is higher in vegetative tissues of Arabidopsis or canola than in seeds of Arabidopsis or canola, and for constructs, vectors, host cells, plants, cell cultures, parts, and propagation material comprising said promoter, does not reasonably provide enablement for a promoter comprising a nucleic acid having 98% identity to SEQ ID NO:1, or for promoter activity in leaves but not seeds of any plants other than Arabidopsis and canola, and for constructs, vectors, host cells, plants, cell cultures, parts, and propagation material comprising said promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The Applicant's arguments in the response filed on Dec. 17, 2009, were fully considered but were not found to be persuasive.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the

amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The nature of the invention is a molecular biological approach for the heterologous expression of recombinant proteins in transgenic plants.

The claims are broadly drawn to a construct comprising a promoter sequence that is a functional equivalent homolog having at least 98% identity to SEQ ID NO:1 or having a fragment of SEQ ID NO:1 comprising a sequence from about base pair 300 to about base pair 583 of SEQ ID NO:1 (which would be 284 base-pairs in length), or a fragment of SEQ ID NO:1 having the promoter activity of SEQ ID NO:1, and to vectors, organisms, plants, cell-cultures, parts, or propagation materials comprising said construct. A "fragment" can be as small as a di-nucleotide.

The Applicants teach the promoter of the Pisum sativum ptxA gene as SEQ ID NO:1 or its complement (see page 4, lines 42-43). They teach that the expression patterns in transgenic Arabidopsis and canola transformed with a construct comprising the ptxA promoter is high expression in seedlings, medium expression in leaves, roots, flowers and seed pods, and no expression in seeds for Arabidopsis; and high expression in seedlings and leaves, medium expression in flowers, low expression in seed pods, and no expression in seeds for Canola (see Table 1 on page

56). The construct in Example 2 is presumed to comprise SEQ ID NO:1, although this is not expressly stated in the specification. They teach motifs that were identified using computer analysis of the nucleotide sequence of SEQ ID NO:1 (see pages 59-60). They teach a construct comprising a chimeric promoter comprising the ptxA promoter and the maize ubiquitin intron, and they teach that the expression pattern from this chimeric promoter is high in embryogenic calli and *in vitro* root, and medium in *in vitro* leaves and plantlets (see Example 17 and Table 3 on page 62).

They do not teach expression patterns for transformed maize past the T_o plantlet stage. They do not teach any nucleic acids with 98% identity to SEQ ID NO:1 that retain promoter activity in leaves but not seeds, other than the nucleic acid of SEQ ID NO:1 itself. They do not teach any expression pattern for a construct comprising only the fragment of SEQ ID NO:1 from position 300 to 583 of SEQ ID NO:1 (as claimed in claim 3 and in part b) of amended claim 1) or any other fragments of SEQ ID NO:1 (as claimed in part (d) of claim 1). They do not teach expression patterns in any plants other than Arabidopsis, Canola, and T_o maize plantlets.

The recitation of a sequence having at least 98% identity to SEQ ID NO:1 encompasses nucleic acids having additions, deletions, substitutions or insertions relative to SEQ ID NO:1. The Applicants do not teach any additions, deletions,

substitutions, or insertions within SEQ ID NO:1 that retain promoter activity equivalent to SEQ ID NO:1.

The state-of-the-art is such that one of skill in the art cannot predict which additions, deletions, substitutions, or insertions within a full-length promoter can be tolerated such that the promoter retains its activity. Mutation of promoter sequences produces unpredictable results. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724). The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

In addition, the promoter of this invention, the ptxA promoter from *Pisum sativum* (SEQ ID NO:1), was discovered and sequenced by David Phillip Bown, and published in his Ph.D. dissertation in 1992 (see Bown, D. P. Thesis, Dept. of Biol. Sci., Univ. of Durham, Durham, UK (1992)). Bown also deposited the complete genomic sequence, including the promoter, in GenBank Accession X67427 (1997). Bown conducted experiments to determine the expression patterns of the endogenous ptxA gene in *Pisum Sativum*, and he determined that it was expressed

strongly in pods, but not in leaves, and only weakly in petals (see second paragraph on page 126; pPP590 is the clone of the ptxA gene). Given this prior art teaching which is in complete opposition to the expression patterns disclosed in Arabidopsis and canola in the instant specification, it is clear that the tissue-specificity of expression from this promoter is different in different plant species. Given this high degree of unpredictability, claims to a particular tissue-specificity are only enabled for the plants in which a tissue specificity has been determined. Note that the experiments in transgenic maize did not proceed past T_o plantlets, therefore, tissue-specificity in stably-transformed maize plants was not determined in the instant application. Note that the fragment recited in claim 3 has not been disclosed to have a particular tissue-specificity in any plant.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to make multitudes of additions, deletions, substitutions, and insertions and test each one for promoter activity and determine what tissues the promoter drives expression in for each species of plant. There is a high degree of unpredictability about which substitutions or deletions would be tolerated.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make and use the claimed

invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

APPLICANT'S ARGUMENTS

The Applicant repeats arguments that have already been addressed in the previous Office Actions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3, 8-15, and 22-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Henkes et al (US 2003/0140380, published on Jul. 24, 2003; and filed as App. No. 10/293,958 on Nov. 12, 2002, with priority to Nov. 9, 2001) as evidenced by Bown, D.P. (GenBank Accession X67427, published on Oct. 29, 1997; pp. 1-3) for the reasons of record stated in the previous Office Action mailed on Mar. 13, 2008. The Applicant's arguments in the response filed on Dec. 17, 2009, were fully considered but were not found to be persuasive.

The claims are drawn to a construct comprising a promoter sequence that is a functional equivalent homolog having at least 98% identity to SEQ ID NO:1 or

comprising a sequence from about base pair 300 to about base pair 583 of SEQ ID NO:1 or comprising a fragment of SEQ ID NO:1, and to vectors, organisms, plants, cell-cultures, parts, or propagation materials comprising said construct.

The instant claims are obvious over the prior art because there was some teaching, suggestion, or motivation in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings, and there was a reasonable expectation of success in combining the teachings.

SCOPE AND CONTENT OF THE PRIOR ART – PRIMARY REFERENCE

Henkes et al teach a construct comprising a "super promoter", a "desired gene", and the NOS polyadenylation signal (see Figure 1). They teach a transgenic plant comprising this construct; including monocots and dicots (see claims 9-12). They teach seeds which are "parts" of plants and are "propagation material" derived from the transgenic plants (see claims 15 and 16). They teach the use of a binary vector for transformation of plants (see paragraph 0098 on page 14). They teach the PtxA promoter from GenBank Accession # X67427 as a stress inducible promoter, and they suggest that it can be used in one of the preferred embodiments of their invention (see paragraph 0107 on page 16). The PtxA promoter is taught along with 16 other possible promoters; therefore it is one member from a list of 17 choices (see paragraph 0107 on page 16).

DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE TEACHINGS OF HENKES ET AL

Henkes et al do not teach the sequence of SEQ ID NO:1, nor do they teach any particular tissue specificity of expression.

SCOPE AND CONTENT OF THE PRIOR ART – SECONDARY REFERENCE

Bown teaches the ptxA promoter (see GenBank Accession X67427) which comprises a sequence that is 100% identical to the instant SEQ ID NO:1 (see sequence alignment).

LEVEL OF ORDINARY SKILL IN THE PERTINANT ART

The pertinent art is the field of molecular biology, and one of ordinary skill in this art would have earned a Ph.D. in molecular biology, biochemistry, plant biology, or some other related field; as evidenced by the skill level of Bown and Henkes, and the co-authors/co-inventors of Henkes. One of ordinary skill in this art would have been well-versed in techniques for heterologous expression of recombinant proteins and would be familiar with the literature encompassing different inducible plant promoters and would appreciate the utility of stress-inducible expression of recombinant proteins.

FINDING OF OBVIOUSNESS

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to combine the teachings of Henkes et al and Bown. These teachings include each element recited in the instant claims, with the exception of the particular tissue-specificity recited. Because Henkes et al teach that it is a preferred embodiment to utilize a stress-inducible promoter and they

specifically suggest the PtxA promoter taught by Bown (see paragraph 0107 on page 16), one of ordinary skill in the art would have been motivated to combine the teachings of Bown and Henkes to arrive at the instant invention. One would have had a reasonable expectation of success for expressing recombinant proteins in response to stress in plants transformed with the construct.

The property of expressing predominantly in leaves in Arabidopsis and canola is an intrinsic property of the ptxA promoter, and therefore, although Bown and Henkes do not teach this property, it would naturally flow from the combination of Henkes et al and Bown. A mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. See *In re Baxter Travenol Labs.*, 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991), where the court held that the fact that another advantage would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

For these reasons, the instant claims are obvious over the prior art.

APPLICANT'S ARGUMENTS

The Applicant repeats some arguments that have been previously presented and addressed in previous Office Actions.

The Applicant asserts that the tissue specificity observed with SEQ ID NO:1 is unexpected (see pages 14-15 of the response). This is not persuasive, however, because none of the claims are limited in scope to SEQ ID NO:1.

Furthermore, the promoter taught by Bown et al in GenBank Accession X67427 comprises the complete sequence of SEQ ID NO:1. Therefore, if the only necessary structural feature of a promoter for providing the particular expression pattern observed is that it comprises SEQ ID NO:1, then this is an intrinsic property of the promoter taught by Bown et al. If, however, it is important that the promoter lack the extra nucleotides taught by Bown et al (nucleotides 1-80 of the nucleic acid of GenBank Accession X67427), in order to be expressed in leaves, then the claims would need to include claim language that excludes the sequence taught by Bown et al, and the Applicant would have to provide evidence that this is the critical element for providing the "unexpected" result. Such evidence is not normally considered after final unless there are good and sufficient reasons why it was not previously presented. If the "unexpected" result is the result of the promoter being transformed into Arabidopsis and Canola rather than being transformed into Pisum sativum; then the Applicant would have to provide evidence that this is the critical element for providing the unexpected result and the claims would be limited to Arabidopsis and Canola plants transformed with the construct. Such evidence is not normally considered after final unless there are good and sufficient reasons why it was not previously presented.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Primary Examiner, Art Unit 1638